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Submitted via Regulations.gov

June 10, 2016

Mr. Michael Goodis
Acting Director, Pesticide Re-Evaluation Division
Office of Pesticides Programs
United States Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: EPA OPP Draft Biological Evaluation of Malathion, Docket Identification No:
EPA-HQ-OPP-2009-0317, 81 Fed. Reg. 21341 (April 11, 2016).

Dear Mr. Goodis:

FMC Corporation (EPA Company No.: 279) and Cheminova A/S (EPA Company No: 4787), appreciate the opportunity to comment on the draft Biological Evaluation (draft BE) for malathion and to address the "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments" (Interim Approaches), released by the Environmental Protection Agency (EPA or the Agency) and the U.S. Fish & Wildlife Service and the National Marine Fisheries Service (the latter two collectively, the Services) on November 13, 2013.

Cheminova A/S (hereafter referred to as "Cheminova") is the sole manufacturer and primary registrant in the United States for the technical form of malathion (CAS Registry Number 121-75-5).

All other registrants of technical malathion obtain their material from Cheminova and all end-use products registered in the United States are produced from Cheminova's technical malathion. In 2015, FMC Corporation (FMC) acquired Cheminova. As such, both companies are "applicants" for ongoing and future consultations on malathion under the Endangered Species Act (ESA).

On April 11th, 2016, EPA released the draft BEs for malathion, chlorpyrifos, and diazinon for public comment in support of registration review of these chemicals. This date marked the start of a 60-day public comment period. The comment period for submission of comments on the draft BEs ends on June 10th, 2016. On April 29th, 2016, a 120-day extension to the comment period was requested by Dow AgroSciences LLC (DAS), Makhteshim Agan of North America, Inc. (ADAMA) and Cheminova to commence after EPA corrected various missing and broken links and provided other missing information that should have been provided with release of the draft BEs. Extension requests were also submitted to EPA by Edward M. Ruckert, representing the American Mosquito Control Association (May 10th, 2016), CropLife America (May 6th, 2016) and James Callan, representing 39 grower groups (May 9th, 2016). EPA responded on May 17th, 2016 by denying the extension. Given its size and complexity, this denial compromised the ability of stakeholders to thoroughly review, evaluate, and prepare a complete set of comments on the draft BEs.

As noted in our joint statement with DAS and ADAMA¹, we have serious concerns about the process under which these draft BEs were prepared. And, we feel, EPA's draft BEs fall far short of being scientifically defensible. One major concern that we have with the draft malathion BE is that in contrast to the National Research Council recommendations (NRC, 2013)², risk quotients (RQs) were

¹ Joint Statement of DOW AgroSciences, LLC., Makhteshim Agan of North America, Inc. ("ADAMA"), FMC Corporation (FMC) and Cheminova A/S (Cheminova) on the Policy Lessons to be Drawn from the Draft OP Biological Evaluations, June 10, 2016. Submitted to the docket on our behalf by David B. Weinberg, Wiley Rein LLP.

² NRC (National Research Council) 2013. Assessing Risks to Endangered and Threatened Species from Pesticides. Committee on Ecological Risk Assessment under FIFRA and ESA, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies, National Research Council of the National Academies. The National Academies Press, Washington, DC. http://www.nap.edu/catalog.php?record_id=18344.

used to determine risk designations in Step 2. RQs can eliminate the negligible risk scenarios, freeing up resources to use probabilistic approaches for the remaining species. However, an ecological risk assessment cannot conclude on the results of a cursory RQ screen. The NRC (2013) specifically stated that “[Risk quotients] are not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes.” The NRC conclusion is consistent with recommendations in the EPA agency-wide guidelines for ecological risk assessment (EPA, 1998)³, which are cited in the NRC report to point out the importance of the explicit treatment of uncertainty during problem formulation (including distributions of values ignored in risk quotients that are better described by probability statements). In direct contrast to this the EPA has maintained its use of RQs, and as will be demonstrated in Section 5, bases species and habitat calls on the most conservative RQs. In contrast to the use of RQs the NRC (NRC, 2013) recommended “using probabilistic approaches that require integration of the uncertainties (from sampling, natural variability, lack of knowledge, and measurement and model error) into the exposure and effects analyses by using probability distributions rather than single point estimates for uncertain quantities. The distributions are integrated mathematically to calculate the risk as a probability and the associated uncertainty in that estimate. Ultimately, decision-makers are provided with a risk estimate that reflects the probability of exposure to a range of pesticide concentrations and the magnitude of an adverse effect (if any) resulting from such exposure.”

Other key concerns identified include:

- A major lack of transparency necessary for evaluation and reproduction of results;
- Use of toxicological measures of effects or attributes that were not empirically linked to apical ecological risk assessment endpoints (mortality, growth and reproduction),

³ EPA (US Environmental Protection Agency). 1998. Guidelines for Ecological Risk Assessment. Office of Research and Development, Washington, DC. EPA/630/R- 95/002F.

- Many studies selected by EPA as threshold values were not evaluated for data quality and relevance, and when evaluated, many evaluations did not follow EPA's own study quality criteria. Use of threshold values from studies deemed invalid by the Agency, or deemed acceptable for quantitative use when criteria for quantitative use were not met;
- Compounding of conservatism of "upper bound" exposure estimate inputs, resulting in unrealistically high deterministic exposure estimates;
- Species calls and critical habitat calls are made assuming that all label uses can be made anywhere in the United States, without drawing any distinctions between use patterns, timing of application, locations and co-occurrence;
- Disparities between exposure durations leading to effects in toxicological studies used to generate thresholds, and field exposure estimates;
- Numerous serious transcription and calculation errors that affected risk designations,
- Use of the newly developed aquatic bin conceptual models resulted in physically impossible malathion EECs for numerous scenarios;
- With the exception of the Agency's overly conservative RQs, other lines of evidence were not directly considered in species and critical habitat calls in the weight-of-evidence tools (e.g., incident reports, field studies, monitoring data, etc.); and,
- EPA gave equivalent "weights" to exceedances of thresholds associated with direct effects to survival, growth or reproduction as they did to exceedances of sublethal thresholds not necessarily linked to adverse effects on individual fitness (e.g., endpoints for avoidance behavior, AChE inhibition, etc.).

Combined, the draft BE estimates nothing less than totally unrealistic, unsupportable catastrophic predictions for the majority of listed species. Yet, as shown with the Kirtland's warbler (KW) example, the size of the Kirtland's warbler population is currently at its historical maximum, which is

nearly 10 times larger than it was at the time of listing and close to twice as large as the threshold stated in the primary objective (FWS, 2012)⁴. The evidence with respect to the recovery and health of the Kirtland's warbler population in the US is clearly inconsistent with the catastrophic risk finding for this species of the highly conservative draft BE for malathion. Similar anomalies between reality and the risks predicted by EPA exist for numerous listed species.

Our technical comments on the draft BE for malathion, are contained in the following documents which we are submitting to the docket:

- Breton, et. al., 2016. Response to EPA's Draft Biological Evaluation for Malathion. Analysis and report prepared by Intrinsic Environmental Science, Inc., and Stone Environmental, Inc. Final report dated June 10, 2016. 472 p.
- Padilla and Winchell, 2016. Refined Malathion Exposure Modeling for Endangered Species in Static Water Habitats: Ohio River Basin HUC 2 Case Study. Analysis and report prepared by Stone Environmental. Project ID: 14-244. Final report dated June 10, 2016. 69 p.
- Moore, et al, 2016. Refined Risk Assessment for the Kirtland's Warbler Potentially Exposed to Malathion. Analysis and report prepared by Intrinsic Environmental Sciences. Final report dated June 10, 2016. 88 p.
- Breton et al., 2016. Refined Effects Determination for Delta Smelt Potentially Exposed to Malathion. Analysis and report prepared by Intrinsic Environmental Sciences and Stone Environmental, Inc. Final report dated June 10, 2016. 498 p.

⁴ FWS (US Fish and Wildlife Service). 2012. U.S. Fish & Wildlife Service. Newsroom. 2012 Marks a Banner Year for Endangered Kirtland's Warblers. <http://www.fws.gov/midwest/news/602.html>. Accessed May 6, 2016.

- Breton et al., 2016. Refined Effects Determination for California Tiger Salamander Potentially Exposed to Malathion. Analysis and report prepared by Intrinsik Environmental Sciences and Stone Environmental, Inc. Final report dated June 10, 2016. 573 p.

Our response document contains initial comments on the technical aspects of the draft malathion BE with focus on assessed aquatic and terrestrial species and exposures. Particular emphasis is given to methods, data used, and assumptions made. In addition, we are providing refined risk assessments for the Kirkland's Warbler, Delta Smelt and the California Tiger Salamander to demonstrate how refined species-specific assessments result in very different conclusions compared to EPA's draft BE for malathion.

These comments are not comprehensive given the limited timeframe for the review. The EPA stated in the letter denying extension of the comment period that the "interim approach is subject to further refinement, and there will be further opportunities for stakeholder feedback in the future." Given the insufficient time for a detailed review of the draft malathion BE, we expect to be provided future opportunities to provide additional comments on the Interim Approaches to the BEs as well as to the malathion draft BE specifically. That said, next week, we are anticipating being able to submit the following three studies to the Agency's document processing desk:

- Bahr, et al, 2016. The Effectiveness of Riparian Vegetation at Intercepting Drift from Aerial Pesticide Application. Final report prepared by the Washington State Department of Agriculture, Natural Resources Assessment Section. Submitted to EPA with permission from the Washington State Department of Agriculture. January 2016. 68 p.
- Gulka, et al, 2016. Malathion – Stream Monitoring for Malathion in The Dalles, Oregon to Parameterize SWAT Model Drift Algorithms. Study conducted and report prepared by Stone Environmental, Inc. Study No.: 15-014. Final report dated June 9, 2016. 10,555 p.

- Donahue, W.A., 2016. In vitro Dose Response Efficacy Evaluation against Twelve (12) Species of Arthropods of a Technical Malathion Serially Diluted in Acetone Applied as a Residual Contact Application to Filter Paper. Sierra Research Laboratories, Inc., SRL Project I.D. # JAG15-1. Final report dated June 10, 2016. 370 p.

Finally, we incorporate into our comments on the draft BE for malathion a number of supportive documents identified in Table 1 (enclosed) that we have previously submitted to the Agency for consideration in preparing the draft BE for malathion.

FMC and Cheminova look forward to engaging with EPA on the issues raised in our comments on the draft BE for malathion. If you have any questions or need additional information, please do not hesitate to contact me at 703-373-8885.

Sincerely,



Paul Whatling

Senior Registration Manager

FMC Corporation

EPA Agent for Cheminova A/S

Enclosures

- c. Steven Snyderman, EPA Chemical Review Manager for Malathion
Kristian Lystbæk, Cheminova A/S
John Cummings, FMC Corporation
Jill Hollihan, FMC Corporation
David Menotti, Crowell and Moring

ENCLOSURE

Table 1: Malathion – Regulatory Documents in Support of Refined Ecological and Endangered Species Risk Assessments

Submitted Document - Reference	Date Submitted	EPA MRID
Habig, C. (2011). Residues of Malathion and Malaoxon on Potential Avian and Mammalian Feed Items. Project Number: WD00255/000/HOT0/2010/001. Unpublished study prepared by Exponent, Inc. 139 p.	03/04/2011	48409301
Breton, R.; Kara, Y.; Moore, D.; et al. (2013). Cheminova's Comments on EPA's Malathion Effects Determination for the California Red-Legged Frog. Unpublished study prepared by Intrinsik Environmental Sciences, Inc. 146p.	09/09/13	49211701
Breton, R.; Rodney, S.; Kara, Y.; et al. (2013). Refined Effects Determination for California Red-Legged Frog Potentially Exposed to Malathion. Unpublished study prepared by Intrinsik Environmental Sciences, Inc. and Stone Environmental, Inc. 1009p.	09/09/13	49211702
Hanzas, J.; Estes, T.; Winchell, M.; et al. (2013). Refined Exposure Modeling of Malathion for the California Red-Legged Frog. Project Number: 112482. Unpublished study prepared by Stone Environmental, Inc. 128p	09/09/13	49211703
Reiss, R. (2013). A Review of Environmental Fate Studies on Malathion and Malaoxon and Application of Current EPA Policies to Derive Inputs for Environmental Modeling. Project Number: 1200734/001/0813/RR20. Unpublished study prepared by Exponent. 36p	9/9/2013	49211704
Johnston, J. (2013). Review for Malathion and Malaoxon in Surface and Ground Water. Unpublished study prepared by Cheminova A/S. 83p.	12/11/2013	49270303
Moore et al., 2014. Avian and Mammalian Dietary Items: Half-lives and Residue Unit Doses for Malathion – Final Report. Analysis and report prepared for Cheminova A/S by Intrinsik Environmental Sciences, Inc. Final report dated May 1, 2014. 96 p.	11/16/2014	49299703
Hillwalker, W.; Reiss, R. (2014). Malathion Technical Material Purity and Impurity Content: Implications for Risk Assessment. Project Number: 1200734/001/5294, CHA100386. Unpublished study prepared by Cheminova, Inc. 293p	02/11/2014	49316501
Breton, R.; Manning, G.; Kara, Y.; et al. (2014). Cheminova's Ecotoxicological Study Evaluation Criteria, Study Evaluations and Proposed Screening-Level Effects Metrics for the Registration Review of Malathion. Project Number: 60320. Unpublished study prepared by Intrinsik Environmental Sciences, Inc. 974p.	03/06/2014	49333901
Moore, D.; Clemow, Y.; Rodney, S.; et al. (2014). Avian and Mammalian Dietary Items: Half-Lives and Residue Unit Doses for Malathion: Final Report. Project Number: 60320, AF/5228/CN, 378/FYF. Unpublished study prepared by Intrinsik Environmental Sciences (US), Inc. and Intrinsik Environmental Sciences, Inc. 96p.	05/23/2014	49389301
Breton, R.; Clemow, Y.; Moore, D.; et al. (2014). Cheminova's Comments on EPA's Preliminary Problem Formulation for Registration Review of Malathion. Project Number: 60320, 000389, 60/FYF. Unpublished study prepared by Intrinsik Environmental Sciences (US) Inc. and Intrinsik Environmental Sciences, Inc. 119p	06/06/2014	49400601
Teed, R.; Rodney, S.; Clemow, Y.; et al. (2015). Cheminova's Comments on EPA's Malathion Effects Determination for Delta Smelt and the California Tiger Salamander: Final Report. Project Number: 60440, AF/5228/CN, 378FYF. Unpublished study prepared by Intrinsik Environmental Sciences, Inc. 200p	08/06/2015	49692201

Submitted Document - Reference	Date Submitted	EPA MRID
Breton, R.; Manning, G.; Greer, C.; et al. (2015). Addendum to Breton et Al. (2014 [MRID 49333901]): Additional Ecotoxicological Data, Updates to Proposed Screening-Level Effects Metrics, and Presentation of Field and Mesocosm Studies for the Registration Review of Malathion. Project Number: 232/112A, 103FYF, 108. Unpublished study prepared by Intrinsic Environmental Sciences, Inc. 180p	08/06/2015	49692301
Pai, N.; Winchell, M. (2016) An Analysis of National Agricultural Malathion Usage From the AgroTrak (2006-2013) Database. Project Number: 14/252. Unpublished study prepared by Stone Environmental, Inc. 79p.	02/19/2016	49841901